**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**

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| IN RE: JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION | MDL Docket No. 2738 |
| This Document Relates To All Cases | |

**DEFENDANTS JOHNSON & JOHNSON AND JOHNSON & JOHNSON CONSUMER INC.'S REPLY IN SUPPORT OF MOTION TO EXCLUDE PLAINTIFFS' EXPERTS' OPINIONS REGARDING ALLEGED HEAVY METALS AND FRAGRANCES IN JOHNSON'S BABY POWDER AND SHOWER TO SHOWER**

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## INTRODUCTION

Plaintiffs' opposition brief highlights the grasping nature of their causation theories in this litigation. Presumably cognizant that the literature on talcum powder does not provide sufficient data to satisfy their burden under *Daubert*, plaintiffs have attempted to bolster their causation theory with a smorgasbord of add-on arguments regarding heavy metals, fragrances and fibrous talc, even though not a single article in the literature even suggests that any of the heavy metals or dozens of fragrances they identify has any relationship to ovarian cancer, or that fibrous talc poses some distinct hazard from platy talc. Remarkably, plaintiffs' response is that the Court should ignore the void in the science because they are merely arguing that heavy metals and fragrances have an "additive" effect to the talc itself. But such an approach has no basis in science, and the fundamental principle underlying *Daubert* is that speculation has no place in the courtroom. Because plaintiffs cannot identify any reliable scientific basis for their experts' opinions on heavy metals, fragrances and fibrous talc, those opinions must all be excluded under *Daubert.*

***First***, plaintiffs argue that the Court should admit expert testimony to the effect that any metal that has been linked with any cancer at any dose poses a risk of ovarian cancer as long as it is present in minuscule levels in cosmetic talcum powder. According to plaintiffs, their experts were not required to identify a dose

at which the metals are allegedly toxic because the Products are a "mixture" of ostensibly hazardous substances whose purportedly carcinogenic nature need only be evaluated "as a whole." In advancing this argument, plaintiffs urge the Court to "***assume*** that there are additive effects" among the alleged heavy metals in the Products, even though not a single expert has even attempted to ***quantify*** the extent to which any of the substances are in fact dose additive. This is speculation, not science. *See Johnson v. Arkema, Inc.*, No. W-09-CV-107, 2010 U.S. Dist. LEXIS 148982, at *43-44 (W.D. Tex. Dec. 16, 2010) (rejecting claim that chemicals plaintiff was exposed to are "dose additive"; although expert "would 'expect' them to be . . . he hasn't 'quantitated' it"; "the dose additive argument is not reliable"), *report and recommendation adopted by* 2011 U.S. Dist. LEXIS 162347 (W.D. Tex. Jan. 26, 2011), *aff'd in relevant part*, 685 F.3d 452 (5th Cir. 2012) (per curiam).

Plaintiffs' argument is also highly disingenuous. If plaintiffs' experts seek to evaluate the products as a whole, then they need to rely on studies involving talcum powder as a whole. Conversely, if they intend to offer opinions that are specific to heavy metals, then they are required to present reliable science regarding the dose of heavy metals in talc and whether any of the metals have been associated with ovarian cancer at those doses. Notably, the only "support" offered in plaintiffs' bid to dispense with dose as a threshold for toxicity is an

Environmental Protection Agency ("EPA") "guidance" document that does ***not*** purport to eliminate the fundamental role of dose as part of any risk assessment inquiry and that, in any event, reflects a risk-mitigation approach to hazard assessment that is not applicable under *Daubert*.

***Second***, plaintiffs' attempt to save their fragrance theory fails for similar reasons. As an initial matter, plaintiffs fail to refute defendants' argument that Dr. Crowley's review was unscientific. Plaintiffs argue that the examples of inconsistencies between Dr. Crowley's opinions and his underlying sources highlighted in defendants' opening brief are "minor" and reflect "nit-picking" by defendants. But far from being "minor" discrepancies, the examples (e.g., Dr. Crowley's confusion over the difference between balsam peru crude and balsam peru extracts and distillates) pertain to fundamental opinions that defendants' Products are not in compliance with governmental and industry standards. Such opinions are plainly unsupported by the very sources cited in Dr. Crowley's own report and should be excluded.

Plaintiffs also largely rehash the same arguments they make with respect to heavy metals, suggesting that they did not need to conduct a proper toxicological assessment of the fragrances because these substances are just part of the whole talcum powder product. These arguments are just as unscientific and legally unsupportable in the fragrance context as they are in the context of heavy metals.

If plaintiffs' experts wish to tell a jury that the fragrances in the Products cause cancer, they must be able to identify studies that link these fragrances to ovarian cancer at the relevant doses. They do not come anywhere close to doing so, as their opposition brief effectively conceded.

Plaintiffs also seek to justify Dr. Crowley's unreliable opinions on the grounds that: (1) it would not be ethically possible to test for the carcinogenicity of fragrance chemicals on human ovaries; and (2) Dr. Crowley purportedly was unable to calculate the levels of the various fragrance ingredients in the Products. These arguments should also be rejected. Any purported ethical limitation on conducting human studies does not shift the burden of proof to defendants; indeed, if that were the case, any time a plaintiff alleged that a product was carcinogenic, the burden would shift to defendants to prove that it was not. And plaintiffs still fail to explain why the information provided by defendants specifying the maximum amount of fragrance chemicals – which, in total, consists of less than one percent of the overall product – did not provide a sufficient basis for Dr. Crowley to determine the maximum concentrations of fragrance ingredients even though defendants' experts, Drs. Kelly Tuttle and H. Nadia Moore, had no difficulty performing these calculations based on the same exact information.

***Third***, plaintiffs attempt to defend their experts' opinions that so-called fibrous talc can contribute to ovarian cancer on the ground that IARC has classified

fibrous talc as being carcinogenic. But as plaintiffs' own brief makes clear, it is talc intergrown with asbestos or crystallized "in ***asbestiform*** habit" that the IARC monographs concluded is carcinogenic. And plaintiffs continue to gloss over this detail in pressing their claim that the Products contain fibrous talc and that such talc can cause ovarian cancer. Because there is no evidence that the merely elongated talc particles plaintiffs' experts Drs. William Longo and Mark Rigler purported to have found in the Products actually were asbestos or had crystallized in an asbestiform habit, plaintiffs' experts' opinions regarding fibrous talc are premised on an erroneous definition and should be excluded.

For all of these reasons, discussed further below, plaintiffs' arguments regarding their experts' opinions related to heavy metals, fragrance chemicals and fibrous talc should be excluded.

## ARGUMENT

### I. PLAINTIFFS' EXPERTS' OPINIONS THAT PURPORTED HEAVY METALS FOUND IN TALC CAN CAUSE OVARIAN CANCER ARE UNRELIABLE.

#### A. There Are No Scientific Studies Linking Heavy Metal Exposure To Ovarian Cancer.

As set forth in defendants' opening brief, plaintiffs' experts' heavy metal opinions should be excluded first and foremost because they cannot identify a single scientific study linking exposure to these metals with ***ovarian*** cancer – the

particular disease at issue in this litigation.[1] Plaintiffs expressly concede that there is a "lack of studies linking the heavy metals specifically to *ovarian* cancer in humans," but nonetheless claim in their opposition that such a dearth of studies is irrelevant to the question of causation based on risk assessments undertaken by various government agencies.[2] This argument is contrary to the law, mischaracterizes the government agencies' approach and, in any event, conflates the kind of risk assessment undertaken by government agencies with the pertinent causation standard that is required in the courtroom under *Daubert*.

***First***, plaintiffs' argument that they need not demonstrate a specific causal link between the alleged heavy metals present in the Products and the ***particular type of cancer at issue in this litigation*** is legally unsupportable. Such an argument reflects a recurring theme of plaintiffs blinding themselves to the fact that cancers have unique etiologies. In fact, "[e]vidence . . . that suggests a connection between . . . exposure and" one type of cancer "is not probative on the causation of" an ***entirely different*** form of cancer. *Allen v. Pa. Eng'g Corp.*, 102

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[1] (*See* Defs.' Mem. of Law in Supp. of Mot. to Exclude Pls.' Experts Ops. re: Alleged Heavy Metals and Fragrances in Johnson's Baby Powder and Shower to Shower ("Defs.' Br.") at 18, May 7, 2019 (ECF No. 9736-4).)

[2] (Pls.' Steering Committee's Mem. In Resp. & Opp'n To Johnson & Johnson and Johnson & Johnson Consumer Inc.'s Mot. To Exclude Pls.' Experts' Ops. re: Alleged Heavy Metals and Fragrances in Johnson's Baby Powder and Shower-To-Shower ("Pls.' Opp'n") at 9-10, May 29, 2019 (ECF No. 9885).)

F.3d 194, 197 (5th Cir. 1996) (Evidence "that suggests a connection between EtO exposure and human lymphatic and hematopoietic cancers" is "not probative on the causation of brain cancer.") (cited in Mem. at 20). Plaintiffs' other briefing in this litigation effectively recognizes as much, arguing that "***different tissues react differently to carcinogens***."[3] And plaintiffs' own expert, Michael Crowley, acknowledged the same principle, testifying that it is possible that an agent can cause one type of cancer but not another.[4] In short, and as elaborated in defendants' opening brief, court after court has barred experts from testifying about causation where – as here – there is no scientific evidence associating exposure to the alleged carcinogen with the "***specific*** disease from which [plaintiff] suffers." *Sutera v. Perrier Grp. of Am. Inc.*, 986 F. Supp. 655, 662 (D. Mass. 1997) (emphasis added).[5]

Plaintiffs do not address this ample case law in their opposition – much less cite any authorities of their own calling for a different approach. Instead, plaintiffs

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[3] (Pls.' Steering Committee's Mem. of Law in Resp. & Opp'n to Defs.' Mot. to Exclude Pls.' Experts' Ops. Related to Biological Plausibility ("Pls.' Bio. Plausib. Opp'n") at 50, May 29, 2019 (ECF No. 9890) (emphases added) (citations omitted); *see also* Pls.' Steering Committee's Omnibus Mem. of Law in Resp. & Opp'n to Defs.' Mot. To Exclude Pls.' General Causation Ops. ("Pls.' Gen. Causation Opp'n") at 178-81 (arguing that "*perineal talc exposure is specifically associated with cancer of the ovary and no other organs*") (citation omitted).)

[4] (Dep. of Michael Crowley, Ph.D. ("Crowley Dep.") 212:14-213:2, Jan. 4, 2019 (attached as Ex. B37 to Tersigni Cert.).)

[5] (*See also* Defs.' Br. at 18-21 (citing cases).)

shift gears, relying on the unremarkable fact that a few government agencies have classified certain alleged heavy metals in the Products as being carcinogenic or possibly carcinogenetic and did so based on an "assessment [that] *is not based on the availability of studies on a specific type of cancer*."[6] According to plaintiffs, IARC's "overall evaluation focuses on carcinogenicity where the agent acts through a 'relevant mechanism,' – findings applicable to ***all organs***, including the ovaries."[7] Essentially, plaintiffs are claiming that when IARC classifies a substance as being carcinogenic or possibly carcinogenic, it is specifying that ***all*** exposures to that substance are carcinogenic or possibly carcinogenic to ***all*** organs. This misrepresents the nature of IARC's assessments.

As the very IARC Preamble cited by plaintiffs makes clear, "[a]n assessment of carcinogenicity involves several considerations of qualitative importance, including . . . the consistency of the results, for example, across species and ***target organ(s)***."[8] Thus, and as plaintiffs are forced to acknowledge, "[s]pecific organs and tissues ***are*** identified where studies have specifically shown increased cancer

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6 (Pls.' Opp'n at 10 (citing Int'l Agency for Research on Cancer, World Health Org., 100C *Monographs on the Evaluation of Carcinogenic Risks to Humans: Arsenic, Metals, Fibres, and Dust* 21, 22 (2012) ("IARC 2012 Monograph") (attached as Ex. A70 to Tersigni Cert.)).)

7 (*Id.* (emphasis added).)

8 (IARC 2012 Monograph at 23 (emphasis added).)

risk."[9] Consistent with this approach, IARC identifies the lung, nasal cavity and paranasal sinuses as tumor sites for certain of the heavy metals plaintiffs claim are in the Products (e.g., chromium VI and nickel), but does ***not*** identify the ovary as a potential target organ.[10] Although IARC's ultimate ***classifications*** are "not target organ oriented," that is so because its mission is to identify carcinogens rather than "classify exposures according to carcinogenicity for specified target organs."[11] In other words, a classification by IARC that a substance is carcinogenic merely reflects IARC's view that there is "***at least one*** target organ for which sufficient evidence of carcinogenicity is judged to exist." Such a classification cannot be construed as a "finding" that the substance in question is carcinogenic to "***all***

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9 (Pls.' Opp'n at 10 (emphasis added).)

10 (IARC 2012 Monograph at 151-167, 169-218; *see also* Straif et al., *A Review of Human Carcinogens—Part C: Metals, Arsenic, Dusts, and Fibres*, 10 Lancet 453, 453 (2009) (attached as Ex. A195 to 2d Suppl. Certification of Julie L. Tersigni ("2d Suppl. Tersigni Cert.")).)

11 Merletti et al., *Target Organs for Carcinogenicity of Chemicals and Industrial Exposures in Humans: A Review of Results in the IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans*, 44 Cancer Res. 2244, 2244 (1984) ("Merletti 1984") (attached as Ex. A191 to 2d Suppl. Tersigni Cert.) (emphasis added).

organs"[12] in light of the fundamental truth that "cancers affecting different organs and systems in humans have different causes."[13]

Similarly, the Agency for Toxic Substances and Disease Registry ("ATSDR") and the National Toxicology Program ("NTP") – other government agencies referred to by plaintiffs – are also solicitous of the specific type of organ at risk as part of their assessments. For example, according to the ATSDR, "[t]he primary targets" of exposure to chromium (VI) "appear to be the respiratory tract, gastrointestinal tract, hematological system, liver, and kidneys."[14] "[T]he primary targets following acute exposure to cobalt include the respiratory system following inhalation exposure . . . the thymus following oral exposure . . . and the immunological system following dermal exposure."[15] And the ATSDR similarly specifies the existing studies on the health effects of nickel by ***organ system*** and

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12 (Pls.' Opp'n at 10 (emphases added).)

13 Merletti 1984 at 2244 (abstract); *see also id.* ("[I]t is of scientific and practical importance not only to identify agents that are carcinogenic to humans but also to specify as definitely as possible the target organ(s) of their action.").

14 Agency for Toxic Substances & Disease Registry, U.S. Dep't of Health & Human Servs., *Toxicological Profile for Chromium*, at 287 (Sept. 2012) (attached as Ex. 23 to Pls.' Opp'n).

15 Agency for Toxic Substances & Disease Registry, U.S. Dep't of Health & Human Servs., *Toxicological Profile for Cobalt*, at 171 (Apr. 2004) (attached as Ex. 24 to Pls.' Opp'n) (citation omitted).

***exposure route***.[16] Notably missing from these discussions is any suggestion that exposure to any of these heavy metals is capable of causing ovarian cancer.

The same is true with respect to the NTP. According to the NTP document cited by plaintiffs, with regard to exposure to chromium (VI), "[t]he data for cancer at sites ***other than the lung and sinonasal cavity were unclear***."[17] Similarly, the data relevant to the NTP's examination of cobalt compounds "were from studies primarily evaluating lung cancer . . . esophageal cancer and other cancers of the respiratory and upper digestive (aerodigestive) tract."[18] And with regard to the alleged carcinogenicity of nickel compounds, the NTP observed that epidemiological studies indicated an "elevated risk" of lung and nasal cancer.[19] As with plaintiffs' reliance on the ATSDR's assessment, plaintiffs are unable to point to anything from the NTP remotely suggesting that exposure to any of the alleged heavy metals in the Products is capable of causing ***ovarian*** cancer.

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16 Agency for Toxic Substances & Disease Registry, U.S. Dep't of Health & Human Servs., *Toxicological Profile for Nickel*, at 171 (Figure 3-5) (Aug. 2005) (attached as Ex. A5 to Tersigni Cert.).

17 Nat'l Toxicology Program (NTP), U.S. Dep't of Health & Human Servs., *14th Report on Carcinogens: Chromium Hexavalent Compounds* (CAS No. 18540-29-9), at 1 (2016) (attached as Ex. 25 to Pls.' Opp'n) (emphases added).

18 *Id.* at 2.

19 *Id.* at 14.

In sum, plaintiffs' effort to excise the role of organ and cancer type from these government agencies' approaches to risk assessment is belied by the very documents cited in their brief.

***Second***, and in any event, a regulatory agency's "prevention-oriented" standards are "materially different" from the standard that must be applied under *Daubert*. *In re Zicam Cold Remedy Mktg., Sales Practices, & Prods. Liab. Litig.*, No. 09-md-2096-PHX-FJM, 2011 WL 798898, at *10 (D. Ariz. Feb. 24, 2011); *see also Rider v. Sandoz Pharm. Corp.*, 295 F.3d 1194, 1201 (11th Cir. 2002) (explaining that regulatory agencies employ a risk-utility analysis that is distinct from the scientific standard demanded by a court, which is "required by the *Daubert* trilogy to engage in objective review of evidence to determine whether it has sufficient scientific basis to be considered reliable"). As a result, even if IARC, the ATSDR and the NTP had ever suggested a link between these chemicals and substances and "cancer" generally, plaintiffs' reliance on their assessments would be no answer to the well-established ***legal*** principle that an expert attempting to prove causation in the courtroom must link the exposure in question to the "***specific*** disease from which [plaintiff] suffers." *Sutera*, 986 F. Supp. at 662 (emphasis added).[20]

[20] According to plaintiffs, "IARC and the ATSDR both noted that the biological activities of all three metals, chromium (VI), cobalt, and nickel, result in *(cont'd)*

For this reason alone, plaintiffs' experts' heavy metal opinions should be excluded under *Daubert.*

### B. Plaintiffs' Experts' Methods Are Unreliable Because They Fail To Address Dosage And Exposure Concentration.

As set forth in defendants' opening brief, plaintiffs' experts' opinions on the alleged relationship between heavy metal exposure and ovarian cancer are independently unreliable because plaintiffs' experts wholly ignore dosage and exposure concentration.[21] Plaintiffs respond that a quantitative dose assessment is not required because this litigation involves "mixtures containing known carcinogens" such that one can just "***assume*** that there are additive effects among the constituents, or 'potential interactions among the components.'"[22] Plaintiffs'

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inflammatory cell responses," which plaintiffs assert "are the same biologically plausible modes of action for Talcum Powder Products and ovarian cancer cited to by the PSC's experts." (Pls.' Opp'n at 12-13.) However, as noted in the opening brief – and as elaborated in defendants' Biological Plausibility brief – there is ***no*** reliable basis for opining that inflammation can cause ovarian cancer at all. (*See* Defs.' Br. at 23 (explaining that the only reliable scientific evidence suggests that inflammation is an effect, and not a cause, of ovarian cancer).)

[21] (*See* Defs.' Br. at 24-31.)

[22] (Pls.' Opp'n at 15 (citing U.S. Envtl. Protection Agency, "Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures," at App. A-7 (Aug. 2000) ("USEPA 2000") (attached as Ex. 26 to Pls.' Opp'n)) (emphasis added); *see also id.* at 22 (plaintiffs asserting that their "experts did not need to conduct a dose response assessment of the individual constituents because they evaluated the Talcum Powder Products as a whole – that is, as a mixture of the constituents").)

argument contravenes well-established toxicological principles and should be rejected.

As the substantial case law cited in defendants' opening brief make clear, the failure of an expert to specify the dose that renders a substance toxic or to confirm that the plaintiff was exposed to such a dose renders a causation opinion scientifically unreliable.[23] Plaintiffs once again fail to even mention (let alone seriously grapple with) these authorites in their brief; nor do they even attempt to cite any cases of their own calling that fundamental principle – the touchstone of toxicology – into question. Instead, plaintiffs assert that "[i]n the case of mixtures containing known carcinogens, the default approach is to ***assume*** that there are additive effects among the constituents, or 'potential interactions among the components."[24] But whether the case involves ***mixtures*** containing purportedly hazardous substances does not alter the analysis. *See Johnson*, 2010 U.S. Dist. LEXIS 148982, at *43-44 (rejecting claim that chemicals plaintiff was exposed to are "dose additive"; although expert "would 'expect' them to be . . . he hasn't 'quantitated' it"; "the dose additive argument is not reliable"); *see also Williams v. Mosaic Fertilizer, LLC*, No. 8:14-cv-1748-T-35MAP, 2016 U.S. Dist. LEXIS

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[23] (*See* Defs.' Br. at 25-26 (citing cases).)

[24] (Pls.' Opp'n at 15 (citing USEPA 2000) (emphasis added).) As discussed *infra*, plaintiffs' characterization of the EPA's "guidance" document is inaccurate.

192236, at *33-34 (M.D. Fla. June 24, 2016) ("Dr. Mink's failure to perform dose-response calculations for any of the constituents" of the emissions and fugitive dust "render his general causation opinions speculative and unreliable."), *aff'd*, 889 F.3d 1239 (11th Cir. 2018).

For example, in *Johnson*, the plaintiff alleged that he was injured while inhaling chemicals emitted by the defendant's coating system equipment. 2010 U.S. Dist. LEXIS 148982, at *1-4. One of the plaintiff's experts opined that the plaintiff had inhaled at least three toxic chemicals emitted by that system: monobutyltin trichloride ("MBTC"), hydrochloric acid ("HCL") and tin oxide, causing him to contract restrictive lung disease and fibrosis. *Id.* at *3-4, *15. In an attempt to salvage the expert's causation opinion, the plaintiff argued that "his exposure to MBTC, HCL and tin oxide in combination created an 'additive toxicity,' increasing the relative risk of harm." *Id.* at *43. "In other words, [the] [p]laintiff claim[ed] that the ***combined*** effect of the toxic components [he] was exposed to would be expected to equate to the toxic effect of a significantly higher level of exposure than just to a single chemical irritant." *Id.* (emphasis added). However, although the plaintiff's expert testified that he would "expect" the chemicals to be additive, he conceded that he had not "quantitated" it. *Id.* at *43-44. Accordingly, and because there was "no evidence that such a dose leads to

severe restrictive lung disease and fibrosis" – the ***specific diseases in question*** – the court resolved that "the dose additive argument [was] not reliable." *Id.* at *44.

So too here. Although plaintiffs contend that "the default approach is to assume there are additive effects among the constituents," ***none*** of plaintiffs' experts has "'quantitated' it," as exemplified by Dr. Judith Zelikoff's testimony (highlighted in plaintiffs' own brief) that "it would be difficult if not impossible" to "analyze the talc separately from the other constituent parts in the products."[25] This fundamental concession, coupled with the utter absence of scentific studies linking any of the allegd heavy metals in the Products to ovarian cancer, renders plaintiffs' "dose additive argument" unreliable.

The only "support" plaintiffs cite in support of their argument is the EPA's Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures, which purports to endorse a "qualitative" – as opposed to "quantitative" – risk assessment.[26] However, plaintiffs' reliance on a "risk assessment process approved by" a government agency[27] is fundamentally misplaced because, as already discussed, a regulatory agency's "prevention-oriented" standards are "materially different" from the standard that must be applied under *Daubert*. *In re*

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25 (Pls.' Opp'n at 15, 22 (citing Dep. of Judith Zelikoff, Ph.D. 271:18-272:4, Jan. 21, 2009).)

26 (*Id.* at 14 (citing USEPA 2000).)

27 (*Id.* at 15.)

*Zicam*, 2011 WL 798898, at *10. Indeed, as the EPA's "guidance" document makes clear, its "primary purpose . . . is to generate a consistent ***Agency*** approach for assessing health risks from exposures to multiple chemicals"[28] – precisely the kind of risk-utility analysis that is different from the scientific standard required by *Daubert*.

In any event, nothing in that document purports to obviate the fundamental consideration of ***dose*** as part of a government agency's risk assessment. Although plaintiffs cite the EPA document as supporting the notion that "the default approach is to ***assume*** that there are additive effects among the constituents" "[i]n the case of mixtures containing known carcinogens,"[29] the document actually specifies that a "risk characterization should discuss each element of the risk assessment paradigm, including available information on the mixture itself, on its components, and on ***potential*** interactions among the components."[30] In other words, even the document cited by plaintiffs (which should have no bearing on the *Daubert* inquiry to begin with) does not remotely support plaintiffs' claim that additive effects can simply be assumed. Instead, it reiterates the "general assumption that interaction effects at low dose levels either do not occur at all or

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28 (USEPA 2000 at 2 (emphasis added).)

29 (Pls.' Opp'n at 15 (emphasis added).)

30 (USEPA 2000 at 11 (emphasis added).)

are small enough to be insigificant to the risk estimate."[31] As a result, the EPA document actually confirms the importance of dosage and undermines plaintiffs' speculative and unscientific "any exposure" approach to causation,[32] which is all the more egregious in this litigation since many of the trace heavy metals allegedly found in talc are also commonly found in the environment.[33]

Plaintiffs also assert that "dose-response and threshold determinations are distinct and separate from the Bradford Hill *biologic plausibility mode of action* that the PSC's experts' opinions are based on."[34] But plaintiffs' focus on biological plausibility with respect to the alleged heavy metals in the Products presupposes the sort of association between those metals and ovarian cancer that would make a Bradford Hill causation analysis appropriate. In fact, plaintiffs have

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31 (*Id.* at 6-7.)

32 (*See* Pls.' Opp'n at 18 (highlighting testimony from Dr. Carson that "any [amount of nickel, chromium, cobalt] within the microenvironment of the inflammatory process that is occurring due to talc sequestration is contributing to the carcinogenic potential") (alteration in original) (citation omitted); *id.* at 19 (highlighting testimony from Dr. Zelikoff that "a single exposure to a certain concentration, whatever that concentration is, can produce effects") (citation omitted).) Notably, plaintiffs do not address the numerous cases cited in defendants' opening brief explaining why such an "any exposure" approach to causation is unscientific and unreliable under *Daubert*. (*See* Defs.' Br. at 28-29 (citing cases).)

33 (*See, e.g.*, Dep. of Arch I. Carson, M.D., Ph.D. 169:24-170:9, Jan. 19, 2019 (attached as Ex. B5 to Tersigni Cert.); *see also, e.g.*, Expert Report of H. Nadia Moore, Ph.D., D.A.B.T., E.R.T. ("Moore Rep.") at 50-68, Feb. 25, 2019 (attached as Ex. C19 to Tersigni Cert.).)

34 (Pls.' Opp'n at 16.)

not presented any epidemiological evidence of any association between any of the metals and ovarian cancer. Accordingly, plaintiffs' discussion of biological plausibility is nonsensical and should be ignored.

For these reasons, too, plaintiffs' arguments fail, and the Court should exclude plaintiffs' experts' opinions that any heavy metals purportedly found in talc can cause ovarian cancer.

### C. Plaintiffs' Experts Ignore The Valence State Of Chromium And The Bioavailability Of Nickel, Further Rendering Their Opinions Unreliable.

#### 1. Chromium

As discussed in defendants' opening brief, plaintiffs' experts either fail to sufficiently consider the differences between trivalent chromium (chromium III) and hexavalent chromium (chromium VI) or do not offer any opinions as to the form of chromium that is allegedly found in talc.[35] This is significant because chromium III is considered non-toxic to humans, whereas chromium VI (although potentially carcinogenic) rarely occurs naturally.[36] In response, plaintiffs devote several pages of their brief to addressing the purportedly carcinogenic nature of chromium VI, which entirely misses the point of defendants' argument.[37] While plaintiffs ultimately attempt to address the actual arguments raised by defendants –

35 (Defs.' Br. at 32-35.)

36 (*Id.* at 32.)

37 (*See* Pls.' Opp'n at 24-27.)

i.e., that plaintiffs' experts either ignored the differences between trivalent and hexavalent chromium or did not offer any opinions as to the form of chromium that is allegedly found in the Products – their responses are meritless.

***First***, plaintiffs assert that "the difference between the valence states is pointed out in numerous PSC's experts' reports."[38] But plaintiffs only cite to the reports of Zelikoff, Krekeler and Smith-Bindman, effectively proving that several of their other experts (e.g., Plunkett and Carson) ***ignore*** the differences between trivalent and hexavalent chromium in their reports. Further, although plaintiffs cite to page 7 of Krekeler's report, he is a mineralogist, not a health expert, and in any event, the discussion of chromium there is limited to highlighting the fact that various government agencies have recognized chromium ***VI*** as a known or potential human carcinogen[39] – which is hardly a discussion about the ***different*** forms of chromium. Thus, even plaintiffs' own citations belie any claim that their experts seriously grappled with the differences between trivalent and hexavalent chromium.

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[38] (Pls.' Opp'n at 27-28 (citing Expert Report of Judith Zelikoff, Ph.D. at 9, Nov. 16, 2018; Expert Report of Mark Krekeler, Ph.D. ("Krekeler Rep.") at 7, Nov. 16, 2019 (attached as Ex. C31 to Tersigni Cert.)); *see also* Smith-Bindman Rep. at 16.)

[39] (Krekeler Rep. at 7.)

***Second***, and in any event, plaintiffs do not dispute that those experts who do acknowledge that chromium exists in different forms do not offer any opinions as to the form of chromium that is allegedly found in talc.[40] Plaintiffs appear to attribute the lack of any such opinions to defendants' own testing procedures, which plaintiffs claim "failed to distinguish between chromium (III) and chromium (VI)."[41] According to plaintiffs, "[h]aving failed to conduct the necessary testing, J&J cannot now ask the court to assume that all chromium found was chromium (III)."[42] But the notion that exposure to alleged ***chromium*** in the Products is capable of causing ovarian cancer is "an issue on which ***plaintiff[s]***" bear "the burden of proof." *Holbrook v. Lykes Bros. S.S. Co.*, 80 F.3d 777, 786 (3d Cir. 1996) (emphasis added) (disproving causation is "a burden which the defense did not bear," whereas "testimony by plaintiff's experts that asbestos exposure caused the cancer [is] an issue on which plaintiff bore the burden of proof"). As such, the onus is on ***plaintiffs***' experts who are pressing a heavy metals theory of causation to link the Products with the particular purportedly carcinogenic form of chromium (chromium VI) on which their opinions depend. *See Veretto v. Williams Field Serv. Rocky Mountain Region Co.*, No. 99-0121 WWD/LCS, 2000 WL 36739884,

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40 (*See* Pls.' Opp'n at 29.)

41 (*Id.*)

42 (*Id.*)

at *3-4 (D.N.M. May 11, 2000) (experts could not rely on reports that some amine compounds have caused respiratory illness to find that a different amine compound caused plaintiff's respiratory illness; "Plaintiff's experts in this case assume there exists, without providing any scientific foundation for it, a bridge between different forms of a chemical compound. This kind of leap is not appropriate under *Daubert* . . . .").

***Third***, plaintiffs' argument that defendants' "internal documents indicate they were aware chromium (VI) was present both in the talc mines *and in the finished products*"[43] is also unavailing. After all, the sole document cited by plaintiffs in support of their claim concerns a ***single*** mine in China and explicitly states that "JJC[I] hasn't use[d] . . . this talc powder batch and it's now blocked."[44] Plaintiffs also cite testimony from a J&J employee purportedly supporting their claim that "[t]he chromium levels measured well over *200 ppm* in many samples of both the talc ore and talcum powder products when J&J's specification limit for chromium . . . was only *0.5 ppm*."[45] That is not what the cited testimony states, but even if it were, the testimony does not speak to the fundamental question of whether the Products contain hexavalent chromium. The same is true with respect

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43 (Pls.' Opp'n at 32.)

44 (JNJ 000131754 at JNJ 000131756 (attached as Ex. 48 to Pls.' Opp'n).)

45 (Pls.' Opp'n at 32 (citing Dep. of Donald Hicks Vol. I 79:1-3, June 28, 2018 (attached as Ex. 55 to Pls.' Opp'n)).)

to evidence that plaintiffs claim indicates "high levels" of heavy metals in samples of finished products. Not only is there no indication of any detection of chromium VI in that evidence, but the supposed detections of chromium range between 251 ppm and 277 ppm,[46] which are "well below [government] screening values" for any kind of chromium, as set forth in the report of defendants' expert, Dr. Tuttle.

Moreover, although plaintiffs also rely on the 1968 study cited by Dr. Zelikoff as supporting the presence of chromium (VI) in Vermont talc mines, defendants explained in their opening brief that not only did the article fail to identify a single one of the products as being a JJCI product, but the levels detected in those as-yet-unidentified products were "of a low magnitude and within a narrow range."[47] The only response offered by plaintiffs is that "J&J has historically held a market share majority for cosmetic Talcum Powder Products."[48] However, such market share is not ***evidence*** that any of the tested products that are the subject of the cited study are the Products actually at issue in this litigation. And even if it were, plaintiffs ignore that the levels of chromium detected were

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46 (*See* JNJ 000237076 (attached as Ex. 6 to Pls.' Opp'n); IMERYS 342524 (attached as Ex. 7 to Pls.' Opp'n).)

47 (*See* Defs.' Br. at 34-35 (quoting Cralley et al., *Fibrous and Mineral Content of Cosmetic Talcum Products*, 29(4) Am Ind Hyg Assoc J. 350, 353 ("Cralley 1968") (attached as Ex. A22 to Tersigni Cert.)).)

48 (Pls.' Opp'n at 33.)

"generally of a low magnitude and within a narrow range."[49] Simply put, the cited study does not support plaintiffs' claim that the Products contain chromium (VI) – much less that they do so in sufficient quantities to cause a risk of ovarian cancer.

For all of these reasons, plaintiffs' experts' failure to meaningfully account for the differences between chromium (III) and chromium (VI) provides additional grounds for excluding their opinions related to alleged heavy metals in the Products.

**2. Nickel**

As discussed in defendants' opening brief, several of plaintiffs' experts also fail to account for the bioavailability of nickel, even though bioavailability bears directly on the purported carcinogenicity of nickel compounds.[50] In response, plaintiffs agree that it "is certainly the case" that the "specific form of nickel" is "important" to assessing whether a particular nickel compound is carcinogenic.[51] Plaintiffs nonetheless take issue with a couple of the animal studies cited by defendants in their opening brief and assert that their experts ***do*** account for the bioavailability of nickel in rendering their opinions.[52] Neither claim has any merit.

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49 Cralley 1968 at 353.

50 (*See* Defs.' Br. at 35-37.)

51 (Pls.' Opp'n at 34 (citation omitted).)

52 (*See id.* at 34-35.)

***First***, plaintiffs argue that "[w]hile it is true that the two animal studies cited by J&J did not indicate any effects on nickel compounds in rats, this is to be expected, because the compound applied in both was *nickel sulfate hexahydrate*," which they claim "ha[s] only 'limited evidence' of carcinogenicity in animals."[53] But plaintiffs miss the point of defendants' citation to those studies, which was merely to illustrate that ***different*** nickel compounds are associated with ***different*** types of tumors – a proposition plaintiffs do not dispute.

***Second***, plaintiffs also argue that their experts accounted for the bioavailability of nickel in forming their opinions.[54] But plaintiffs do not – and cannot – point to any example of an expert addressing this subject in his or her report. Instead, they appear to assert that because their experts "considered, in part, the analyses of agencies such as IARC and the NTP" – which "base their carcinogenicity analyses on many types of relevant data" – they necessarily factored the bioavailability of nickel into their opinions.[55] But whether IARC and the NTP took the bioavailability of nickel into consideration in making ***their*** assessments says nothing about what plaintiffs' experts did in this litigation. In short, plaintiffs have no evidence that any of their experts actually accounted for

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53 (*Id.* at 34 (citing IARC Monograph 2012 at 211).)

54 (*Id.* at 35.)

55 (*Id.*)

the fact that different nickel compounds are associated (if at all) with different types of tumors.

For all of these reasons, plaintiffs are unable to refute defendants' arguments that plaintiffs' experts' opinions regarding heavy metals are separately unreliable because they ignored the specific chemical forms of the heavy metals supposedly found in talc.

## II. DR. CROWLEY'S OPINION THAT THE FRAGRANCES USED IN JJCI'S TALCUM POWDER CONTRIBUTE TO THE PRODUCTS' CARCINOGENICITY LACKS FOUNDATION.

### A. Dr. Crowley's Opinions Are Not Based On A Reliable Methodology.

As explained in defendants' opening brief, Dr. Crowley's opinions are unreliable because they are at odds with the very sources he cites in his report.[56] In response, plaintiffs seek to minimize defendants' arguments as nothing more than "nit-picking at minor discrepancies."[57] But the gaps between the sources Dr. Crowley relies on and his ultimate and fundamental conclusions as to whether the fragrance chemicals are in compliance with government and industry standards reflect a glaring failure in his overall methodology and not mere trivial errors that can be sorted out at trial.

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56 (*See* Defs.' Br. at 38-43.)

57 (Pls.' Opp'n at 50.)

Plaintiffs argue that "any mistakes in Dr. Crowley's report should be addressed in cross examination, not result in the wholesale exclusion of his opinions."[58] But an opponent's ability to meet unreliable expert evidence with reliable counter-evidence and strong cross-examination does not relieve a district court of its gatekeeping responsibilities. *See Lithuanian Commerce Corp. v. Sara Lee Hosiery*, 179 F.R.D. 450, 458-59 (D.N.J. 1998) ("I find that it was error for Judge Rosen, in exercising his gatekeeping function, to premise his determination of admissibility on Sara Lee's ability to rebut the proffered testimony."). Instead, "district courts must evaluate proffered expert evidence in the first instance rather than leaving the task for the jury to sort through" and ensure that expert testimony satisfies the "minimum requirements of reliability." *Id.* at 459-60 (because the expert misinterpreted the data underlying his opinion, his opinion had an "inadequate foundation" and was unreliable); *see also Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 158 (3d Cir. 1999) ("[I]t is surely within the court's province to ensure that the conclusion . . . 'fits' with the data alleged to support it.").[59]

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[58] (*Id.* at 49 n.187.)

[59] The only case cited by plaintiffs – *Voilas v. General Motors Corp.*, 73 F. Supp. 2d 452 (D.N.J. 1999) (cited in Pls.' Opp'n at 49) – is utterly inapposite. In that case, the expert failed to "evaluate ***all*** available options" in valuing plaintiffs' employment opportunities. *Id.* at 462 (emphasis added). According to the court, the failure to consider every single alternative was merely a "shortcoming" that could be addressed by the defendant's counsel during cross-examination rather than a core infirmity implicating the expert's overall reliability. *Id.*

Even a cursory review of Dr. Crowley's report and deposition reveals that his opinions do ***not*** meet the "minimum requirements of reliability" because the sources on which he relies do not support his ultimate conclusions. Indeed, plaintiffs expressly concede that Dr. Crowley's opinion that the Products contain an ingredient prohibited for use in fragrances and cosmetics – hardly a trivial claim – rests on his confusion of balsam peru crude and balsam peru extracts and distillates.[60] Although plaintiffs seek to downplay Dr. Crowley's confusion as a "simple misunderstanding,"[61] such misapprehension of the very sources he cites resulted in Dr. Crowley's fundamental opinion that the ingredients in the Products "are not approved for use in a fragrance" and "are not in compliance with governmental and industry standards."[62]

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60 (*See* Pls.' Opp'n at 49 (acknowledging that Dr. Crowley ultimately agreed that balsam peru extract/distillate was used in Johnson's Baby Powder and not the "prohibited" balsam peru crude).)

61 (*Id.* at 48.)

62 (*See, e.g.*, Expert Report of Michael M. Crowley, Ph. D. ("Crowley Rep.") at 11, 64, Nov. 12, 2018 (attached as Ex. C34 to Tersigni Cert.).) Plaintiffs also expressly concede that defendants are "correct that coumarin, eugenol, and D-limonene" "have IARC Group 3 classifications" (Pls.' Opp'n at 43), which means that such fragrances are "***not*** classifiable as to [their] carcinogenicity . . . in humans," Int'l Agency for Research on Cancer, World Health Org., *Monograph on the Evaluation of Carcinogenic Risk to Humans: Preamble* 23 (2006) (attached as Ex. A73 to Tersigni Cert.) (emphasis added); and that the most recent assessment of pre-cresol "concluded that there is ***inadequate*** information to assess [that fragrance's] carcinogenic potential." (Pls.' Opp'n at 47 (emphasis added).)

Similarly, as explained in defendants' opening brief, Dr. Crowley also misleadingly claimed that the FDA had decided to remove benzophenone from use in foods "due to histiocytic sarcoma observed in ovaries and uterus" along with other adverse effects found in animal studies.[63] In their opposition, plaintiffs double down on Dr. Crowley's claim, pointing to Dr. Crowley's deposition testimony, in which he asserted that the NTP study underlying the FDA's decision "concluded that benzophenone caused cancer."[64] But the FDA, in evaluating that same NTP study, expressly found that "benzophenone is ***unlikely to induce tumors in humans at current use levels***." Food Additive Regulations; Synthetic Flavoring Agents and Adjuvants, 83 Fed. Reg. 50,490, 50,495 (Oct. 9, 2018) (emphasis added). Accordingly, the agency concluded that benzophenone "d[id] ***not*** pose a risk to public health under the conditions of [its] intended use." *Id.* at 50,490, 50,502 (emphasis added). Dr. Crowley's reliance on the 2006 NTP study that he cites in support of his claim regarding the FDA's action with regard to benzophenone highlights the "gap between the data and the opinion proffered," and renders his testimony "likely to lead the factfinder to an erroneous

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63 (Defs.' Br. at 41 (citation omitted); Crowley Rep. at 48 (citations omitted); *see also* Crowley Rep. at 65.)

64 (*Id.* at 46 (citing Crowley Dep. 277:21-278:16).)

conclusion." *In re TMI Litig.*, 193 F.3d 613, 666 (3d Cir. 1999) (citation omitted), *amended in nonmaterial part*, 199 F.3d 158 (3d Cir. 2000).

In sum, Dr. Crowley's erroneous conclusions are far from "simple misunderstanding[s]" that the Court should toss to the jury to evaluate. Rather, as the examples discussed above illustrate, the errors highlighted in defendants' opening brief are part and parcel of Dr. Crowley's core opinions in this case – i.e., "whether the fragrance chemicals are in compliance with government and industry standards."[65] And because those opinions do not reliably flow from the sources he cites in support of them, they do not satisfy the "minimum requirements of reliability" and should be excluded. *Lithuanian Commerce Corp.*, 179 F.R.D. at 159-60.

### B. Dr. Crowley's Opinions Are Also Unreliable Because There Is No Scientific Evidence Linking Fragrance Exposure To Ovarian Cancer.

As set forth in defendants' opening brief, Dr. Crowley's fragrance opinions should be excluded because – as he admits – there is not a single study linking any of the fragrances in the Products to ovarian cancer in humans.[66] In response, plaintiffs argue that: (1) it is not ethically possible to test the purported

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65 (Pls.' Opp'n at 37.)

66 (Defs.' Br. at 43-48; *see also* Crowley Dep. 114:9-15 ("Q. Are you aware of any publication that links the fragrance chemicals in baby powder and Shower to Shower to ovarian cancer? A. I don't believe I found a source that made that association.").)

carcinogenic or toxic effect of the chemicals on humans; and (2) studies demonstrate a link between some of the fragrances and alleged toxicity and/or carcinogenicity in humans.[67] Once again, plaintiffs' arguments are meritless.

***First***, plaintiffs argue that "it is not ethically possible to test for the carcinogenicity and toxicity of chemicals on human ovaries – studies can *only* be performed on animals."[68] But the purported "animal" studies relating to "ovarian abnormalities" that plaintiffs claim their experts rely on are not, in fact, animal studies.[69] Rather, these studies are *in vitro* studies that examine "the effects of a chemical on human or animal cells, bacteria, yeast, isolated tissues, or embryos."[70] As the Toxicology Reference Manual recognizes, "[r]elatively few" *in vitro* tests "have been validated by replication . . . or by comparison with outcomes in animal studies to determine if they are predictive of whole animal or human toxicity."[71] Perhaps for this reason, courts have warned that "[c]aution always must be used in extrapolating results in tissue culture to effects in live humans." *In re Rezulin Prods. Liab. Litig.*, 369 F. Supp. 2d 398, 428-29 (S.D.N.Y. 2005); *see also In re*

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67 (Pls.' Opp'n at 50-55.)

68 (*Id.* at 50.)

69 (*Id.* at 51-52.)

70 Goldstein & Henifin, Fed. Judicial Ctr., *Reference Guide on Toxicology*, *in Reference Manual on Scientific Evidence* 633, 645 (3d ed. 2011) ("Toxicology Reference Manual") (attached as Ex. A46 to Tersigni Cert.).

71 *Id.*

*Abilify (Aripiprazole) Prods. Liab. Litig.*, 299 F. Supp. 3d 1291, 1310 (N.D. Fla. 2018) (because "the chemical reactions that occur in the artificial environment of a test tube or petri dish may differ from how the drug will react in, and impact, the complex biological system that is the human body," "*in vitro* evidence alone cannot serve as a basis for a general causation opinion").[72]

Moreover, defendants articulated multiple specific reasons why extrapolating the results from the Chinese hamster ovary cell studies highlighted in plaintiffs' brief to human ovaries would be especially unreliable,[73] none of which plaintiffs address in their brief. As one court aptly recognized in rejecting an expert's reliance on hamster cell studies in attempting to prove general causation in humans, such cells are "highly susceptible to uncontrolled cell division, the distinguishing characteristic of cancer." *Mancuso v. Consol. Edison Co.*, 56 F. Supp. 2d 391, 403, 410 (S.D.N.Y. 1999) ("[E]ven if perfectly designed and executed, [the tests] could only have shown that some component of mud samples from the marina caused sister chromatid exchanges in specially prepared mouse and hamster cells."), *aff'd in relevant part*, No. 99-9233, 2000 U.S. App. LEXIS

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[72] Indeed, when "confronted with questions of toxicity," courts have even recognized the "limited usefulness" of ***animal*** studies. *Johnson v. Arkema, Inc.*, 685 F.3d 452, 463 (5th Cir. 2012) (per curiam) ("[S]tudies of the effects of chemicals in animals must be carefully qualified in order to have explanatory potential for human beings.") (citations omitted).

[73] (Defs.' Br. at 48 (quoting Moore Rep. at 89).)

12487 (2d Cir. June 5, 2000). In short, any ethical limitations on conducting human studies do not relieve plaintiffs' experts of their burden of "connect[ing] the dots" from the studies they ***do*** cite to human ovarian cancer – a burden they did not come close to carrying. *C.W. ex rel. Wood v. Textron, Inc.*, 807 F.3d 827, 837 (7th Cir. 2015) (although "[t]hese studies are unavailable because of the ethical and moral concerns of introducing toxins to children," the experts failed "to connect the dots from the studies" they ***did*** cite "to the illnesses endured by the children").

***Second***, plaintiffs alternatively argue that "studies ***do*** exist demonstrating a link between some of the fragrance chemicals . . . and toxicity and/or carcinogenicity in humans."[74] But some of those studies do not even support plaintiffs' ***general*** proposition about cancer in the abstract, and none of them pertains to ***ovarian cancer in particular***. For example, plaintiffs assert that "[t]he safety of Cresols was reviewed by the World Health Organization in 1995," which supposedly "concluded there is clear evidence in humans that during dermal or oral exposure, high concentrations of Cresols are corrosive, absorb rapidly, and produce severe toxicity that may result in death."[75] But plaintiffs conveniently do not

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[74] (Pls.' Opp'n at 53.)

[75] (*Id.* (quoting Final Report on the Safety Assessment of Sodium *p*-Chloro-*m*-Cresol, *p*-Chloro-*m*-Cresol, Chlorothymol, Mixed Cresols, *m*-Cresol, *o*-Cresol, *p*-Cresol, Isopropyl Cresols, Thymol, *o*-Cymen-5-ol, and Carvacrol, 25(Suppl. 1) Int J Toxicol. 29, 30 (2006) ("2006 *p*-Cresol Study") (attached as Ex. 60 to Pls.' Opp'n)).) Plaintiffs' reliance on a study addressing harm purportedly posed by *(cont'd)*

mention that the same report found that "[t]here is ***no information*** regarding the chronic toxicity of Cresols and ***no adequate data*** regarding the carcinogenic potential of these compounds."[76]

More fundamentally, however, none of the studies highlighted by plaintiffs purports to tie even a single fragrance in the Products to ***ovarian*** cancer in particular. Rather, as plaintiffs expressly recognize, these other studies examined potential effects on human skin cells and other tissues.[77] Particularly in light of Dr. Crowley's own recognition that an agent can cause one type of cancer but not another,[78] the studies highlighted in plaintiffs' opposition brief say nothing about whether the fragrances in the Products are capable of causing the "***specific*** disease from which [plaintiffs] suffer[]." *Sutera*, 986 F. Supp. at 662 (emphasis added). Accordingly, and for the reasons discussed in connection with plaintiffs' experts' heavy metals opinions, the lack of scientific evidence connecting any of the

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"high concentrations of Cresols" is all the more illogical in light of the low amounts of fragrances in the Products, as elaborated *infra*.

[76] (2006 *p*-Cresol Study at 30 (quoting World Health Org., Cresols, 168 WHO Environ. Health Criteria 1 (1995)) (emphases added).)

[77] (*See* Pls.' Opp'n at 53 (referencing study examining purported cytotoxic effect of lavender oil on human skill cells *in vitro*); *id.* (noting that the 1995 study of cresols examined dermal and oral exposure); *id.* at 54 (referencing study observing "menstrual disorders and hormonal disturbances").)

[78] (Crowley Dep. 212:14-213:2.)

fragrances to ovarian cancer renders plaintiffs' experts' opinions on this topic speculative and inadmissible.

### C. Dr. Crowley's Failure To Analyze Dosage Further Renders His Opinions Inadmissible.

As explained in defendants' opening brief, Dr. Crowley's fragrance opinions are separately inadmissible because he did not even attempt to estimate the level of exposure to fragrance ingredients that would be necessary to cause harm.[79] Plaintiffs offer two arguments in response: (1) Dr. Crowley was unable to conduct such an assessment because defendants "did not supply the necessary information for such an analysis"; and (2) such an analysis was not required, in any event, for the same reasons proffered by plaintiffs in connection with their experts' heavy metals opinions.[80] Both arguments are without merit.

***First***, plaintiffs argue that Dr. Crowley could not have quantified a dose because defendants "provided limited, incomplete information about the fragrance chemicals in [the] products" – i.e., the documents "do not specify the ***precise*** amount of each individual chemical in the products, but only 'relative portions.'"[81] However, as extensively addressed in defendants' opening brief, maximum and minimum concentrations of fragrance ingredients in the Products were specified in

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79 (*See* Defs.' Br. at 58-63.)

80 (*See* Pls.' Opp'n at 55-61.)

81 (*Id.* at 56 (emphasis added).)

the documents provided to plaintiffs.[82] Thus, although "precise" amounts were not listed, maximum exposure levels can be easily derived.

Plaintiffs also contend that Dr. Crowley "explained why it is not appropriate to hazard a guess about dosage and exposure," pointing to the following testimony:

> So, for example, cinnamal has a Category 5 restriction of 0.05 percent. Since I don't know how much is present, I can't make a judgment as to whether the cinnamal present in *Baby Powder* exceeds 0.05 percent or not. There's a bunch of other fragrance chemicals here too that have these restrictions similar to *Shower-to-Shower*. Let's save each other some time. ***I can't make that judgment*** because your client hasn't given me the information to be able to do that.[83]

But this testimony proves nothing more than Dr. Crowley's unwillingness to contend with the fundamental concept of dose. After all, because both maximum and minimum amounts were provided to plaintiffs for a given volume of product, one can easily estimate the maximum possible exposure to each fragrance ingredient – a straightforward calculation that defendants' toxicology expert Dr. Tuttle did, ***including with respect to the specific fragrance chemical identified in the aforementioned testimony***.[84] For example, with respect to cinnamal, Dr. Tuttle readily determined that the percentage of the chemical fell between 0.000011-

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82 (*See* Defs.' Br. at 52-53.)

83 (Pls.' Opp'n at 56 (quoting Crowley Dep. 330:15-331:2) (emphasis added).)

84 (*See* App. D to Expert Report of Kelly Scribner Tuttle, Ph.D., CIH ("Tuttle Rep.") at 67, Feb. 25, 2019 (attached as Ex. C26 to Tersigni Cert.); *see also* Tuttle Rep. at 67.)

0.00022 percent – far below the restriction set by the International Fragrance Association that the chemical not comprise more than 0.05% of a product.[85] Dr. Tuttle performed the same straightforward assessment with respect to each of the other fragrances, culminating in her conclusion that "[n]one of the[] chemicals is present in the talcum powder products at issue at levels that would warrant a health or regulatory concern."[86] Defendants' other expert, Dr. Moore, similarly had no trouble "ascertain[ing] the maximum percentage of each fragrance ingredient" in the Products,[87] and concluding that all "were within the use limits and do not pose an increased risk of adverse health effects, including ovarian cancer."[88] Notably, these assessments, which were central points in Dr. Tuttle's and Dr. Moore's reports – were not challenged in plaintiffs' Motion to Exclude the Opinions of Defendants' Toxicology Experts, effectively conceding their reliability.[89] Simply put, Dr. Crowley's failure to quantify the level of exposure to fragrance ingredients

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85 (Pls.' Opp'n at 56.)

86 (Tuttle Rep. at 53.)

87 (Moore Dep. 327:25-238:3; *see also id.* 328:20-329:3.)

88 (Moore Rep. at 71; *see also* Fragrance Ingredients, as set forth in the Complete List of Materials Reviewed and Considered by H. Nadia Moore, Ph.D., DABT, ERT, as of Apr. 3, 2019 (attached as Ex. I4 to 2d Suppl. Tersigni Cert.).)

89 (*See generally* Pls.' Steering Committee's Mot. to Exclude the Ops. of Defs.' Toxicology Experts Brooke T. Mossman, M.S., Ph.D., Kelly S. Tuttle, Ph.D. and H. Nadia Moore, Ph.D., May 7, 2019 (ECF No. 9874).)

that would be necessary to cause harm was the result of his own unwillingness to do so rather than any incompleteness in the documents provided to plaintiffs.

***Second***, there is likewise no truth to plaintiffs' alternative argument that Dr. Crowley "did not need to" to analyze the dosage in opining that the fragrances are purportedly carcinogenic.[90] Plaintiffs largely rehash the same arguments "discussed above regarding heavy metals,"[91] which fare no better when offered in connection with fragrances. In the main, plaintiffs contend that "the proper methodology for mixtures is a non-threshold model with consideration given to the ***additive*** effects of the components."[92] For example, plaintiffs claim that at least one of the fragrance chemicals at issue – p-cresol – is "co-carcinogenic," which supposedly "means it has been found to 'promote tumors in animals when co-administered with a known carcinogen.'"[93] Of course, this example says nothing about the various other fragrant chemicals that are addressed in Dr. Crowley's report. In any event, the example confirms, rather than undermines, defendants' arguments about dosage.

As explained by defendants' expert Dr. Tuttle, although "the definition of co-carcinogen can vary in the scientific literature," it "is typically applied to

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90 (Pls.' Opp'n at 57.)

91 (*Id.*)

92 (*Id.* (emphasis added).)

93 (*Id.* at 59 (citing Crowley Dep. 212:9-13).)

promoters" of inflammation.[94] Importantly, however, "[a]s with any promoter, the inflammation itself does not cause cancer, but rather promotes cell growth, ***requiring multiple prolonged exposures of a sufficient threshold***."[95] Put another way, even assuming plaintiffs' flawed understanding of the role of inflammation in cancer were correct, "the role of a threshold dose has been shown to apply not only to mutagens, but to . . . co-carcinogens."[96] As a result, even assuming that a chemical like p-cresol "*can increase*" talc's purportedly carcinogenic activity with respect to human ovaries at any dose,[97] (for which Dr. Crowley presented ***zero*** evidence), Dr. Crowley would have had to opine on the dose at which it does so and to quantify whether that dose can be satisfied through talcum powder usage. *See Johnson*, 2010 U.S. Dist. LEXIS 148982, at *43-44 (rejecting "dose additive argument" where expert failed to quantify the extent to which the chemicals in question "created an 'additive toxicity'").[98]

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94 (Tuttle Rep. at 13.)

95 (*Id.* (emphases added).)

96 (*Id.* at 55.)

97 (Pls.' Opp'n at 59.)

98 Plaintiffs also press Dr. Crowley's opinion that certain of the fragrance chemicals are genotoxic, such that "dose response is immaterial." (Pls.' Opp'n at 60.) However, as discussed in defendants' opening brief, even if it were established that a particular fragrance were genotoxic, that fact would not be sufficient to classify the material as carcinogenic – a proposition plaintiffs do ***not*** dispute in their opposition brief. (*See* Defs.' Br. at 54.) In any event, and as also explained in defendants' opening brief, studies of the genotoxicity of ethanol have *(cont'd)*

For all of these reasons, Dr. Crowley's opinions about any purported relationship between the fragrances used in the Products and ovarian cancer should be excluded.

### D. The Opinions Of Plaintiffs' Experts Parroting Dr. Crowley Should Also Be Excluded.

As set forth in defendants' opening brief, the Court should also exclude the opinions of plaintiffs' experts who parrot Dr. Crowley's opinions regarding fragrance chemicals.[99] Plaintiffs' only response is that because Dr. Crowley's "opinions are supported by ample scientific data . . . there is no basis for excluding any other of the PSC's experts' opinions that relate to or rely on Dr. Crowley's opinions."[100] But plaintiffs fundamentally miss the point of defendants' argument, which is that "[a] scientist . . . is not permitted to be the mouthpiece of a scientist in a different specialty." *Dura Auto. Sys. of Ind., Inc. v. CTS Corp.*, 285 F.3d 609, 614 (7th Cir. 2002). Thus, even assuming Dr. Crowley's opinions were reliable (and they are not, for all of the reasons discussed above), that still would not give

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reported effects at some levels of exposure but not others (*see id.* at 54-55), proving Dr. Tuttle's point that "dose plays a ***key*** role in assessing the genotoxicity of a compound." (Tuttle Rep. at 12 (emphasis added).) Plaintiffs do not even respond to these studies in their brief, relying solely on Dr. Crowley's *ipse dixit* that genotoxic materials "don't have a threshold." (Pls.' Opp'n at 61 (quoting Crowley Dep. 125:20-126:1).)

99 (*See* Defs.' Br. at 55-56.)

100 (Pls.' Opp'n at 61.)

plaintiffs' ***other*** experts license to simply parrot those opinions – an approach plaintiffs do not even attempt to deny the other experts have taken in this litigation. Accordingly, the Court should exclude all of plaintiffs' other experts' opinions related to fragrances in the Products.

## III. PLAINTIFFS' EXPERTS' OPINIONS THAT THE PRODUCTS CONTAIN CARCINOGENIC FIBROUS TALC SHOULD BE EXCLUDED BECAUSE THEY ARE BASED ON AN ERRONEOUS DEFINITION.

Finally, as set forth in defendants' opening brief, the Court should also exclude plaintiffs' experts' opinions related to fibrous talc because they fundamentally misconstrue IARC's views on this topic, which are aimed at talc that contains, or is intergrown with, true asbestos or that grows in an asbestiform habit – minerals that plaintiffs' experts have not purported to find in the Products.[101] Plaintiffs respond that "IARC devoted multiple Monograph reviews to" fibrous talc "in order to *clarify* any confusion regarding the definition."[102] But the very definition highlighted in plaintiffs' brief proves exactly why their experts' opinions on this topic should be excluded. As discussed in plaintiffs' own brief, IARC has limited its classification to "'***asbestiform*** fibers,' which is defined by

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101 (*See* Defs.' Br. at 57-62.)

102 (Pls.' Opp'n at 62.)

IARC as any mineral, including talc, when it grows in an ***asbestiform*** habit."[103] Further, as plaintiffs recognize, "'asbestiform fibers' can be either asbestos or ***asbestiform*** (fibrous) talc."[104]

The core problem with plaintiffs' experts' opinions is that neither those experts nor plaintiffs in their opposition brief are able to tether the opinions to this fundamental definition. Plaintiffs assert that Dr. Longo and their other experts all "use consistent definitions for 'fibrous talc,'" – i.e., "talc with asbestiform fibers or asbestiform talc."[105] However, the only consistency on the part of plaintiffs' experts and the limited evidence they cite is the repeated disregard for the "asbestiform" component of IARC's definition. Indeed, Dr. Longo testified that he did not differentiate between fibers that are "nonasbestiform versus asbestiform."[106] Plaintiffs also point to "internal documents as evidence of the presence of fibers or fibrous talc," including an internal analysis supposedly

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[103] (*Id.* at 63 (quoting Int'l Agency for Research on Cancer, World Health Org., 93 *Monographs on the Evaluation of Carcinogenic Risks to Humans: Carbon Black, Titanium Dioxide, and Talc* 39 (2010) ("IARC 2010 Monograph") (attached as Ex. A72 to Tersigni Cert.)) (emphases added).)

[104] (*Id.* at 64 (emphases added); *see also id.* at 67 ("Both IARC, 2012 and IARC, 2010 were dedicated to expounding on definitions *for the inclusion of fibrous talc (talc in **asbestiform habit**) as a carcinogen*.") (bold emphasis added).)

[105] (*Id.*)

[106] (Dep. of William E. Longo, Ph.D., 225:1-4, Feb. 5, 2019 (attached as Ex. B48 to Tersigni Cert.); *see also id.* 226:17-24 ("It doesn't give you the information to make the determination. Just like it doesn't give you the information to determine if you have high tensile strength.").)

showing that fibrous talc was present "in up to **10% of the talc ore** from the Hammondsville Mine in Vermont."[107] But that internal analysis – as with Longo's opinions – does not purport to identify any of the talc as being asbestos or having grown in an asbestiform habit.[108] As a result, that document is not remotely supportive of the opinions that fibrous talc supposedly present in the Products is capable of causing ovarian cancer.

In sum, and particularly given IARC's unequivocal statement that fibers "may . . . be elongated ***without being asbestiform***" and therefore without being dangerous,[109] plaintiffs' experts' singular focus on the purportedly fibrous (i.e., elongated) nature of talc particles says nothing about whether they are actually dangerous. And the absence of evidence that any of the allegedly fibrous talc in the Products was asbestos or grew in an asbestiform habit should necessarily

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107 (Pls.' Opp'n at 67.)

108 (*See* JNJS7IR_000001978-2016-2031 (attached as Ex. 64 to Pls.' Opp'n).)

109 (IARC 2010 Monograph at 277 (emphases added).) Plaintiffs argue that defendants "improperly quoted IARC, 2010" in their opening brief because IARC "*actually* indicates that the six listed minerals (actinolite, anthophyllite, chrysotile, grunerite, riebeckite and tremolite) may be elongated without being asbestiform—not talc." (Pls.' Opp'n at 66.) Not so. According to the passage in question, "***[s]imilarly to talc***, these six minerals occur more commonly in a non-asbestiform habit, and may also be elongated without being asbestiform." (IARC 2010 Monograph at 277 (emphasis added).) The clear import of this discussion under any fair understanding of the English language is that talc also exhibits these same characteristics.

preclude plaintiffs' experts from opining about so-called fibrous talc in this litigation.[110]

## CONCLUSION

For the foregoing reasons, and those set forth in defendants' opening brief, the Court should exclude the opinions proffered by plaintiffs' experts regarding alleged heavy metals, fragrances or fibrous talc that are set forth on the following pages of plaintiffs' experts' reports:

- Pages 5-8 of the Expert Report of Arch Carson;
- Pages 6 and 9 of the Expert Report of Daniel Clarke-Pearson;
- Pages 2, 4, 9-10, 20-26 and 40 of the Expert Report of Robert Cook;
- The entirety of the Expert Report of Michael Crowley;
- Pages 5, 29 and 36 of the Expert Report of Sarah Kane;
- Pages 19 and 21 of the Expert Report of David Kessler;
- Pages 23-30 and 45 of the Expert Report of Mark Krekeler;
- Pages 15-17 of the Expert Report of Shawn Levy;
- Page 15 of the Expert Report of William Longo and Mark Rigler;

[110] Plaintiffs also stress in bold that "**J&J's argument that the mineral forms identified as fibrous [in internal documents] *are not fibrous* contradicts the documents and has no basis in fact.**" (Pls.' Opp'n at 68.) However, plaintiffs fundamentally misperceive defendants' argument, which is that none of plaintiffs' experts "provide[d] any basis to assume that any of these fibers were asbestos, or even asbestiform." (Defs.' Br. at 61.) Such a fundamental misunderstanding of defendants' argument mirrors plaintiffs' experts' misapprehension of IARC's review of asbestiform fibers and serves to underscore the unreliability of plaintiffs' experts' opinions regarding fibrous talc.

- Pages 8-9 and 56-57 of the Expert Report of Anne McTiernan;
- Pages 17-21, 23-24, 25-26, 46, 53, 55, 67-69 and 77-78 of the Expert Report of Patricia Moorman;
- Pages 17-21, 23-26, 46, 53, 55, 67-69 and 77-78 of the Expert Report of Laura Plunkett;
- Pages 65-66 of the Expert Report of Jack Siemiatycki;
- Pages 15-16 and 60 of the Expert Report of Sonal Singh;
- Pages 18-19 and 21-22 of the Expert Report of Ellen Blair Smith;
- Pages 5, 14-16 and 40 of the Expert Report of Rebecca Smith-Bindman;
- Pages 9-10 and 15-16 of the Expert Report of Judith Wolf; and
- Pages 4, 8-12 and 27 of the Expert Report of Judith Zelikoff.

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Respectfully submitted,

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